**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF NEW YORK**

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| Nancy Calchi, individually and on behalf of all others similarly situated,<br><br>*Plaintiff*,<br><br>v.<br><br>GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, GSK Consumer Health, Inc., and Pfizer Inc.<br><br>*Defendants*. | Lead Case No. 7:22-cv-01341-KMK<br><br>**JURY TRIAL DEMANDED** |
| Stacey Papalia, on behalf of herself and all others similarly situated,<br><br>*Plaintiff*,<br><br>v.<br><br>GlaxoSmithKline Consumer Healthcare Holdings (US) LLC,<br><br>*Defendant*. | Case No. 7:22-cv-02630-KMK |

**Consolidated Class Action Complaint**

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## I. Introduction.

1. Defendants make, distribute, sell, and market "Robitussin" over-the-counter cough and flu medicine. Several Robitussin products contain the active ingredient Dextromethorphan Hydrobromide ("DXM"). At least 16 Robitussin products containing DXM prominently state on the front of their label that they are "Non-Drowsy." [1]

2. By prominently labeling these products as "Non-Drowsy," Defendants led Plaintiffs and other consumers to believe that the Non-Drowsy Robitussin Products do not cause drowsiness, and that drowsiness is not a side effect of those products. Consumers rely on this "Non-Drowsy" medicine when they are driving, working, and supervising their children (when being drowsy would be problematic or even dangerous). But the truth is that the Non-Drowsy Robitussin Products do cause drowsiness, and Defendants know this.

3. In this way, Defendants misled Plaintiffs and other reasonable consumers about the effects of the Non-Drowsy Robitussin Products. Defendants' misrepresentations allowed them to overcharge Plaintiffs and other consumers for the Non-Drowsy Robitussin Products.

## II. Parties.

4. Plaintiff Nancy Calchi is a citizen of New York (domiciled in Bloomingburg).

5. Plaintiff Stacey Papalia is a citizen of New York (domiciled in Ossining).

6. The proposed class(es) include citizens of numerous states.

7. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC is a citizen of Delaware and New Jersey. It is a Delaware corporation with its principal place of business in Warren, New Jersey.

[1] Throughout this Complaint, Robitussin products containing DXM that state on their label that they are "Non-Drowsy" are called "Non-Drowsy Robitussin Products."

8. Defendant GSK Consumer Health, Inc. is a citizen of Delaware and New Jersey. It is a Delaware corporation with its principal place of business in Warren, New Jersey.

9. Defendant Pfizer, Inc. is a citizen of Delaware and New York. It is a Delaware corporation with its principal place of business in New York, New York.

## III. Jurisdiction and venue.

10. This Court has subject matter jurisdiction under 28 U.S.C. § 1332(d)(2). The amount in controversy exceeds the sum or value of $5,000,000, exclusive of interest and costs, and the matter is a class action in which one or more members of the proposed class(es) are citizens of a state different from the Defendants.

11. Defendants have purposefully marketed and sold hundreds of thousands (and potentially millions) of Non-Drowsy Robitussin Products to New York consumers, including Plaintiffs.

12. Venue is proper under 28 U.S.C. § 1391(b)(1) and 28 U.S.C. § 1391(d) because Defendants would be subject to personal jurisdiction in this District if this District were a separate state, given that Defendants sold the Non-Drowsy Robitussin Products to consumers in this District, including Plaintiffs. Venue is also proper under 28 U.S.C. § 1391(b)(2) because a substantial part of Defendants' conduct giving rise to the claims occurred in this District, including selling Non-Drowsy Robitussin Products to Plaintiffs.

## IV. Facts.

### A. Defendants make, market, distribute and sell Robitussin products prominently labeled "Non-Drowsy."

13. The GSK Defendants [2] manufacture, distribute, market, and sell the Non-Drowsy

[2] GSK refers collectively to GSK Consumer Health and GlaxoSmithKline Consumer Healthcare Holdings.

Robitussin Products, and have done so since mid-2019. Prior to that, Pfizer manufactured, distributed, marketed, and sold the Non-Drowsy Robitussin Products.

14. According to Pfizer's filings in other cases, Pfizer "no longer owns the rights to the Products, and any potential liability it may have had for the Products has been transferred to GSK pursuant to a Stock and Asset Purchase Agreement." Defendants' Answer to Plaintiff's First Amended Class Action Complaint at 1-2, *Moore v. GlaxoSmithKline Consumer Healthcare Holdings (US) LLC*, 4:20-cv-09077-JSW (N.D. Cal. Aug. 20, 2021). If this representation is true, GSK is responsible, and liable for, the distribution, marketing, and sale of the Non-Drowsy Robitussin Products at all relevant times. [3]

15. In the alternative, GSK is responsible, and liable for, the distribution, marketing, and sale of the Non-Drowsy Robitussin Products since mid-2019, and Pfizer is responsible, and liable for, such distribution, marketing, and sale beforehand.

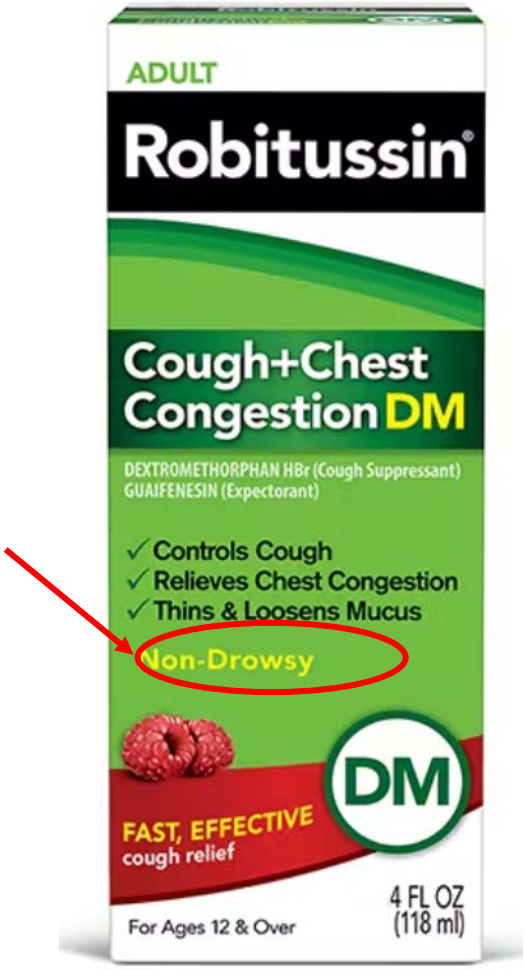
16. The Non-Drowsy Robitussin Products that Defendants distributed, marketed, and sold, and continue to distribute, market, and sell, include: Robitussin Honey Cough + Chest Congestion DM; Robitussin Maximum Strength DM Day/Night Pack; Robitussin Maximum Strength DM Day/Night Pack; Robitussin Maximum Strength Severe Multi-Symptom Cough Cold + Flu; Robitussin Maximum Strength Severe Multi-Symptom Cough Cold + Flu Pack; Robitussin Maximum Strength Severe Cough + Sore Throat; Robitussin Maximum Strength Cough & Chest Congestion DM Capsules; Robitussin Cough + Congestion DM; Robitussin Sugar-Free Cough + Chest Congestion DM; Robitussin Multi-Symptom Cold CF; Robitussin Long-Acting CoughGels; Robitussin Maximum Strength Honey Severe Cough, Flu + Sore Throat, Robitussin Children's Cough & Chest Congestion DM; Robitussin Children's Cough &

[3] If GSK stipulates that it will assume all liability for Defendants' acts throughout the relevant timeframe, Plaintiffs are willing to dismiss Pfizer from the case.

Cold CF; Robitussin Children's Honey Cough & Chest Congestion DM; and Robitussin Children's DM Day/Night Pack.

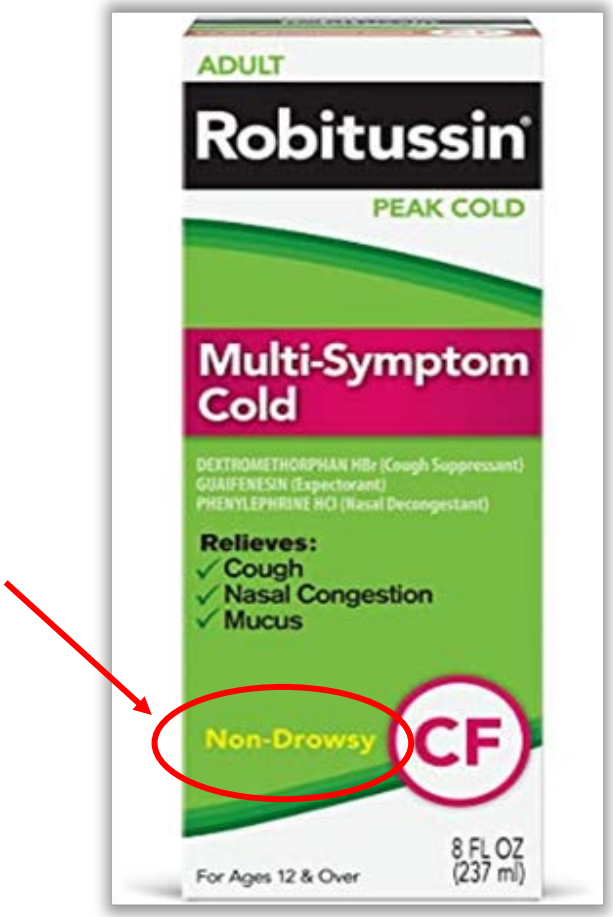
17. The front label of each Non-Drowsy Robitussin Product prominently states that the product is "Non-Drowsy." For example:

**Cough + Chest Congestion DM** [4]



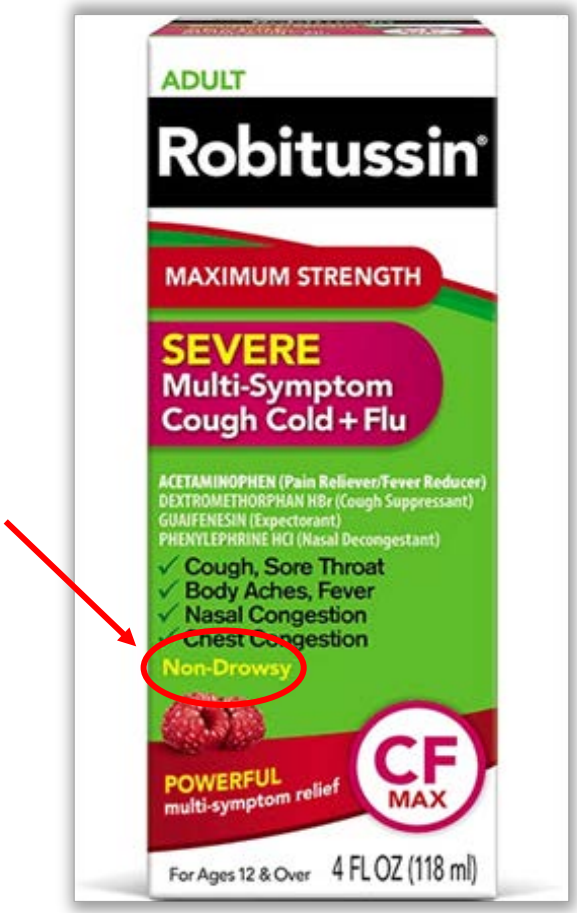

[4] https://www.robitussin.com/adult-robitussin/cough-chest-congestion-dm/

**Multi-Symptom Cold CF** [5]




[5] https://www.robitussin.com/adult-robitussin/multi-symptom-cold-cf/

**Multi-Symptom Cough Cold + Flu** [6]




18. These representations are materially the same across all Non-Drowsy Robitussin Products. That is, all Non-Drowsy Robitussin Products are substantially similar.

19. Based on the prominent "Non-Drowsy" label included on the face of each product, a reasonable consumer would believe that the products do not cause drowsiness. That is, a reasonable consumer would believe that drowsiness is *not* a side-effect of the product.

[6] https://www.robitussin.com/adult-robitussin/maximum-strength-severe-multi-symptom-cough-cold-flu/

20. Defendants labeled the products this way because they intended consumers to rely on the labels and to believe that the products would not cause drowsiness, so that consumers would buy more products or pay more for them.

**B. The Non-Drowsy Robitussin Products cause drowsiness.**

21. In truth, products containing DXM—like the Non-Drowsy Robitussin Products—do cause drowsiness, and drowsiness is a documented side effect of DXM. For example, MedlinePlus, a medical library published by the NIH National Library of Medicine, warns that "drowsiness" is a "side effect" of DXM. [7] This is true both at the recommended doses and (unsurprisingly) for overdoses.

22. As a second example, a peer-reviewed study found that "[s]omnolence is a common side effect of centrally acting antitussive drugs" like dextromethorphan, and that 10.4% of users of products containing dextromethorphan develop drowsiness within three days of starting treatment with DXM cough medicine. [8, 9] The "cases of intense somnolence" were "related only to dextromethorphan" and not to the other drug studied. And patients in this clinical study were given an even smaller dosage of DXM (15 mg three times a day) than the recommended dose found in many Robitussin products. [10]

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[7] Dextromethorphan: MedlinePlus Drug Information, NIH National Library of Medicine, https://medlineplus.gov/druginfo/meds/a682492.html (listing drowsiness as a side effect). The NIH offers Medline Plus for the public to find "reliable health information." https://www.nlm.nih.gov/portals/public.html

[8] E. Catena and L. Daffonchio, "Efficacy and Tolerability of Levodropropizine in Adult Patients with Non-productive Cough, Comparison with Dextromethorphan," 10 Pulmonary Pharmacology & Therapeutics 89-96 (1997).

[9] The study reports this side effect as "somnolence." Somnolence means "the quality or state of being drowsy." Merriam Webster Dictionary, https://www.merriam-webster.com/dictionary/somnolence

[10] For example, Robitussin Cough + Chest Congestion DM contains 20 mg of DXM per 20 ml of syrup and the recommended dosage is 20 ml orally every 4 hours. https://www.robitussin.com/adult-robitussin/cough-chest-congestion-dm/

23. In fact, drowsiness is a very common side effect at the recommended dosages. According to a 2017 GSK presentation on drug labeling, a "common" adverse reaction (i.e., side effect) is one that occurs in 3% or more of drug takers and a "very common" side effect occurs in 10% or more of drug takers.

24. The FDA's adverse event report database confirms that "sedation" is one of the most frequently-cited side-effects of dextromethorphan-containing products. [11]

25. Because DXM causes drowsiness, the Federal Aviation Administration prohibits pilots from flying after ingesting medicines that contain DXM: [12]

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| **Cough** | Cough/cold products | Coricidin (allowed if no chlorpheniramine)<br><br>guaifenesin (found in Mucinex and Robitussin)<br>Mucinex fast-max severe congestion and cough (liquid)<br><br>Identify combo vs isolated | dextromethorphan (Delsym)<br><br>Dayquil (contains dextromethorphan)<br><br>Most "night-time" or "PM" medications contain a sedating antihistamine:<br>- Coricidin HBP cough & cold (contains chlorpheniramine)<br>- Nyquil (contains doxylamine) | Most cough medications are safe for flight, but caution for combination products with sedating antihistamines. **If the label states PM (for nighttime use) or DM (containing dextromethorphan), you should not fly for at least 5 half-lives after the last dose (see above).** |

26. As shown above, the FAA cautions against both (1) "combination products" that have "sedating antihistamines" for "night-time" use and, independently (2) purportedly daytime cough medicines that contain DXM. For example, the FDA specifically warns against Dayquil and Delsym, DXM drugs that are antihistamine free. This is because, as the FAA has recognized, DXM causes drowsiness.

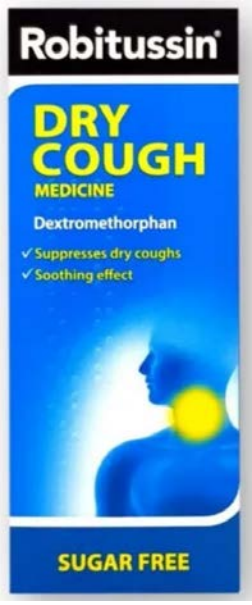
27. Defendants are well aware that drowsiness is a common side effect of the Non-Drowsy Robitussin Products.

[11] Even "minimal" sedation is associated with drowsiness. *See* https://www.medicinenet.com/sedation_vs_general_anesthesia/article.htm

[12] https://www.faa.gov/licenses_certificates/medical_certification/media/OTCMedicationsforPilots.pdf

28. Pfizer issued a safety data sheet for Robitussin in 2015. That data sheet states: "Common adverse reactions associated with the clinical use of dextromethorphan hydrobromide include … drowsiness." [13] So Pfizer has admitted that "drowsiness" is a common side effect of products that Defendants market as "Non-Drowsy."

29. In the United Kingdom, GSK sells Robitussin DXM products that are comparable to the Non-Drowsy Robitussin Products that GSK sells in the United States. For example, Robitussin Dry Cough, sold in the UK:




30. For this medicine, GSK is required by UK regulators to write a "patient leaflet" that describes the side effects of normal use. The leaflet, written by GSK states that "side effects" include "drowsiness." [14] The leaflet also states that the medicine "can affect your ability to drive" because it may "make you sleepy." Likewise, GSK's product information lists

[13] https://imgcdn.mckesson.com/CumulusWeb/Click_and_learn/SDS_9PFIZ_ROBITUSSIN_DM_SYRP_4OZ.pdf
[14] MHRA Patient Leaflet, Robitussin Dry Cough Medicine, https://mhraproducts4853.blob.core.windows.net/docs/7c5537ae627a6e58ab33052924cb807c887886f0

"drowsiness" as a side effect. [15]

31. What is true about the UK version of Robitussin with DXM—that it causes drowsiness—applies more forcefully to the US version. The UK version contains a *lower* recommended dosage of DXM, compared to the US version. In the UK, the recommended single dosage is 15 mg of DXM. In the US, the recommended dosage is 20 mg of DXM (33% more DXM, compared to the UK version). So the risk of drowsiness is even greater for the US version. Despite this, Defendants falsely claim that the US version is "Non-Drowsy," while affirmatively warning that the UK version causes drowsiness.

32. As illustrated above, the UK package for Robitussin Dry Cough (with DXM) lacks the false "Non-Drowsy" claim that appears in the US. In contrast, for UK Robitussin medicines that do *not* contain DXM and that truthfully do not cause drowsiness, GSK includes the "Non-Drowsy" claim. For example, the "Non-Drowsy" claim appears on Robitussin Chesty Cough, which has only Guaifenesin (and not DXM):


[15] https://www.gskhealthpartner.com/en-gb/respiratory-health/brands/robitussin/products/cough-range/

33. The point here is *not* that the US versions should be required to have a drowsiness warning. As explained in more detail below, that is not what Plaintiffs seek. Instead, the point is that, on the US versions, Defendants are voluntarily making an affirmative claim that they know to be false: that Robitussin products with DXM are "Non-Drowsy." It is this affirmatively false "Non-Drowsy" claim (and not the lack of a warning) that forms the basis of Plaintiffs' claims.

**C. Defendants' Non-Drowsy representations are false and misleading.**

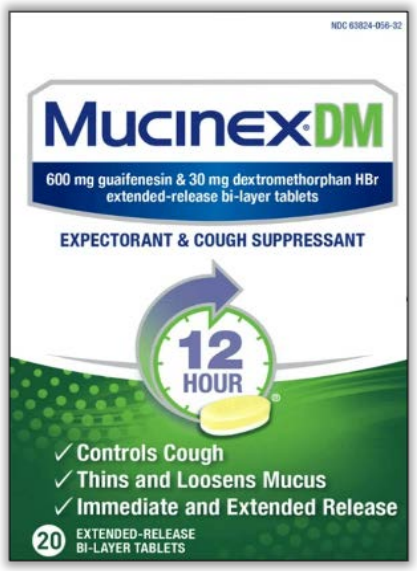
34. Based on the fact that Defendants label the Non-Drowsy Robitussin Products as "Non-Drowsy," a reasonable consumer acting reasonably under the circumstances would expect that those products do not cause drowsiness. Similarly, a reasonable consumer would expect that drowsiness is not a side effect of the products. According to Consumer Reports, "'Non-drowsy' is code for antihistamines and other medications that don't make you sleepy." [16] This is the plain meaning of "non-drowsy," which means "not causing or accompanied by drowsiness." [17]

35. Defendants' prominent "Non-Drowsy" claim makes it difficult for consumers to realize that they are being misled. Consumers who get drowsy while taking the Non-Drowsy Robitussin Products will reasonably (but wrongly) conclude that those products did *not* cause their drowsiness because of the reassuring (but false) "Non-Drowsy" claim. As a result, consumers keep taking dose after dose of the product, with adverse and potentially dangerous results. Put another way, even if consumers try to figure out the cause of their drowsiness, the last source they will identify is the Non-Drowsy Robitussin, because Defendants affirmatively tell consumers that this medicine is *not* the cause of their drowsiness.

36. Unlike Defendants, some other drug makers don't falsely claim that DXM

[16] "How to read over the counter (OTC) drug labels," Consumer Reports, https://www.consumerreports.org/cro/2014/04/how-to-read-over-the-counter-drug-labels/index.htm
[17] https://www.merriam-webster.com/medical/nondrowsy

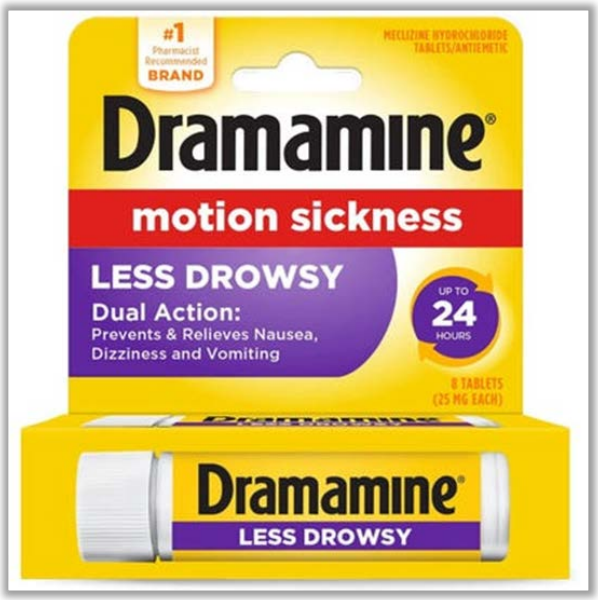
products are non-drowsy. For example, DXM is an active ingredient in Reckitt's Mucinex DM. But the Mucinex label does not claim to be "non-drowsy," because this is not the truth:




37. Defendants could have simply omitted the false and misleading statement, "Non-Drowsy," from their products.

38. Or, if Defendants wanted to say something to indicate that a Non-Drowsy Robitussin Product might cause less drowsiness than another Robitussin product, they could have made a truthful statement to this effect, as other drug makers do.

39. For example, Dramamine contains an active ingredient that causes drowsiness, Dimenhydrinate. Dramamine also sells a "less drowsy" version that contains a different active ingredient, Meclizine, which causes less drowsiness. The front label of Dramamine Less Drowsy prominently displays that it is "less drowsy":




40. Whether or not an over-the-counter drug causes drowsiness is material to a reasonable customer. In certain situations, consumers prefer over-the-counter drugs that will not make them drowsy to products that may make them drowsy. For example, all else being equal, a reasonable consumer would prefer to take a drug that does not cause drowsiness to one that does cause drowsiness during the day (or any periods of time when they plan to be awake). As a second example, if a consumer is planning to engage in activities that require them to be alert (like work), or during which they would prefer to be alert, that consumer would prefer to take a drug that does not cause drowsiness to one that does. Indeed, in many situations, taking a drug that does or can cause drowsiness can be dangerous. For example, taking a drug that causes drowsiness while driving, or flying a plane, is dangerous.

41. Defendants know that the "Non-Drowsy" label misleads reasonable consumers. As explained in detail above, in the UK, GSK tells consumers the truth: that Robitussin with DXM causes drowsiness. But in the US, Defendants knowingly and intentionally say the opposite: that Robitussin with DXM is "Non-Drowsy." For these reasons, Defendants knew that its labeling was false and misleading, or was reckless or willfully blind to this fact. Defendants

intended that consumers would rely on the "Non-Drowsy" labeling, so that consumers would purchase more products and pay a price premium.

42. Because the Non-Drowsy Robitussin Products actually do cause drowsiness, Plaintiffs and each class member did not get what they paid for: a cough medicine that does not cause drowsiness. Instead, they received something that is worth less: a cough medicine that does cause drowsiness. Plaintiffs and each class member sustained economic injuries for this reason, i.e., they received something worth less than the price they paid for it.

43. Defendants' false statements increased the demand for Non-Drowsy Robitussin Products and allowed Defendants to charge a price premium. As explained above, consumers specifically value the "Non-Drowsy" claim because consumers demand cough medicine that will not make them drowsy (e.g., during the day, at work or while driving). As a result, Defendants were able to charge more for these products than they would have been able to had the labeling been truthful. Accordingly, as a direct result of Defendants' false statements, Defendants were able to charge a price premium for these products. As purchasers, Plaintiffs and each class member paid this price premium and sustained economic injury.[18]

44. For example, on the CVS website, a bottle of "Non-Drowsy" Robitussin Maximum Strength Cough + Chest Congestion DM is currently priced at $10.99 (for 8 ounces). This price is artificially inflated by the misleading "Non-Drowsy" claim. If this misleading claim was removed, demand would drop, which in turn would reduce the market price. This price premium can be quantified (i.e., a dollar figure measured) using expert economic analysis of data that includes, among other things, sales and pricing information uniquely within the possession of Defendants.

[18] This is not a personal injury case, and Plaintiffs do not seek any recovery in this action for personal injuries. As described above, the injury here is economic.

45. Moreover, the Non-Drowsy Robitussin Products are marketed and sold specifically for "Non-Drowsy" use, i.e., for use in situations where consumers do not want to risk drowsiness. As a result, the products that Plaintiffs and each class member did receive in exchange for the price they paid—Non-Drowsy Robitussin Products that cause drowsiness — were not suitable for, and were thus worthless for, their intended purpose. So the economic injury Plaintiffs and each class member sustained consists of the entire purchase price of the products.

**D. Plaintiffs were misled by Defendants' misrepresentations**

46. In or around the end of fall/beginning of winter, 2021, Ms. Calchi bought Robitussin Cough + Chest Congestion DM from a ShopRite in Middletown, New York. The package said "Non-Drowsy" prominently on the label, and Plaintiff read and relied on this statement when purchasing the product. But when Plaintiff took the recommended dose of the medication as directed on the label by Defendants, she became unexpectedly drowsy. Plaintiff was not on any other medication that would have caused this drowsiness, and there was no other potential cause for this drowsiness, aside from the ingredients in the Robitussin medication. Plaintiff would not have bought this product had she known that the product did, in fact, cause drowsiness, and that drowsiness was a known side-effect of the product. The price Plaintiff paid for the Robitussin medication was inflated due to the misleading "Non-Drowsy" label, for the reasons set forth above. In fact, because the product causes drowsiness, it is worthless to her.

47. In or around October 2021, Ms. Papalia bought Robitussin Cough + Chest DM from a Walgreens in Ossining, New York. The package said "Non-Drowsy" prominently on the label, and she read and relied on this statement when purchasing the product. Based on the label, Ms. Papalia believed that the product would not cause drowsiness and that drowsiness is not a side effect. In reliance on the label, Ms. Papalia drove her car while she was taking the

Robitussin medicine. She would not have bought this product had she known that the product did, in fact, cause drowsiness, and that drowsiness was a known side-effect of the product. The price she paid for the product was inflated due to the misleading "Non-Drowsy" label, for the reasons set forth above. In fact, because the product causes drowsiness, it is worthless to her.

**E. The FDA has never approved Defendants' false Non-Drowsy claim.**

48. The Food and Drug Administration prohibits drug labeling that is "false or misleading." 21 C.F.R. § 201.6. It is misleading to label a product "Non-Drowsy" when it does cause drowsiness, or if drowsiness is a known side effect of one of its active ingredients.

49. Plaintiffs are not seeking to require Defendants to add any additional warning or disclosure to the label. Instead, Plaintiffs seek to require Defendants to remove the misleading "Non-Drowsy" statement that Defendants have voluntarily added to sell more products and to overcharge consumers.

50. No FDA regulation allows cough medicines containing DXM to be labelled "Non-Drowsy" and the FDA has never considered whether this claim is false and misleading. (Nor would the FDA ever approve such a claim, because it is in fact false and misleading).

51. For certain over-the-counter drugs like Defendants' cough syrups, the FDA issues regulations known as monographs. Monographs identify the active ingredients that can be marketed for certain uses (for example, cough remedies). *E.g.*, 21 C.F.R. § 341.1. They also set forth all of the required disclosures and warnings that must be included on the label. *E.g.*, 21 C.F.R. § 341.74. The required disclosures generally include a "statement of identity" (the name of the product and what kind of medicine it is, for example a cough suppressant); the use "indications" for the product; the warnings that must be included; and the directions for safe use. *Id.*

52. Monographs do not, however, catalog every conceivable labelling claim and say

whether it is prohibited or allowed, truthful or deceptive. *See generally* 21 C.F.R. §§ 341 et. seq. Nor does the FDA individually review every statement on over-the-counter drug labels to ensure that they are truthful and not misleading, before approving the drug for sale. Instead, FDA regulations simply provide that the label must comply with the general requirements of the Act, including the general prohibition on "false or misleading" labelling statements. 21 § C.F.R 330.1 (in addition to complying with the monograph, drug must be "labeled in compliance with chapter V" of the Act); 21 U.S.C. § 352 (Chapter V of the Act). And the FDA generally does not police over-the-counter labels to ensure compliance with this requirement.

53. Here, the governing cough medicine monograph does not require, expressly approve, or even mention the "Non-Drowsy" statement. *See* 21 C.F.R. § 341.74. Nor do the regulations discuss or approve any substantially similar statement, such as "Non-Sleepy" or "does not make you drowsy." *Id.* In contrast, the cough syrup monograph does expressly authorize other statements to be made on the label of cough syrups like Defendant's products. 21 C.F.R. § 341.74(b)(3) (identifying optional statements that "the labeling of the product may contain"). For example, it expressly authorizes the label of cough medicines to say "Temporarily helps you cough less." *Id.* If the FDA had authorized "Non-Drowsy," then "Non-Drowsy" would be on the list of authorized statements. It isn't.

54. To be sure, the cough medicine monograph does not mandate that products with DXM contain a drowsiness warning. But this does not show (or even suggest) that the FDA approved an affirmative "Non-Drowsy" claim.

55. In declining to require a drowsiness warning, the FDA never concluded that DXM does not cause drowsiness. Like any other regulator, when the FDA decides what warnings to require, it uses its discretion in deciding which limited set of warnings is crucial, based on the best information available at the time. In other words, the FDA asks which dangers are so

extreme, and so clear, as to be crucial to warn the public about. By declining to require a warning, the FDA is not saying that a risk is immaterial to consumers. That logic is dangerous and absurd.

56. For example, the Consumer Product Safety Commission requires products of certain dimensions to include a "CHOKING HAZARD" warning on their label if they are marketed to toddlers. 16 C.F.R. § 1500.20. This is because objects of these dimensions are most likely to cause choking deaths. But it does not mean that the Commission determined that these are the only products that can cause choking. That inference would allow companies to market toys slightly larger than the threshold dimensions to toddlers and affirmatively claim on the package: "NOT A CHOKING HAZARD." But permitting this false assertion would cause deaths. Ex. A (Characteristics of Objects that Cause Choking in Children, JAMA 274:1763 at 1766, col. 1 (1995)) (Over 1 in 7 nonfood choking deaths are caused by objects larger than the dimensions that trigger the warning requirement). The Commission focused its warning on certain dimensions because they presented the gravest danger of choking, not because it found that all other dimensions present no material danger.

57. As a second example, the cough syrup monograph itself does not require medicines containing DXM to include an affirmative warning to avoid alcoholic beverages (this warning is required for other cough medications, 21 C.F.R. § 341.74). But elsewhere, the FDA warns consumers to "[a]void alcohol if you are taking…cough-cold products with the ingredient dextromethorphan." [19] Again, the Commission used its discretion to decide that it was not necessary to include this warning on the label. The lack of a mandatory label warning does not tell us that according to the FDA, it is perfectly safe to consume alcohol while taking DXM.

[19] https://www.fda.gov/drugs/choosing-right-over-counter-medicine-otcs/over-counter-medicines-whats-right-you.

58. This same logic applies to the lack of a drowsiness warning. In the 1980s, when the FDA issued the cough medicine monograph, the FDA was "not aware of data demonstrating that … dextromethorphan … require[s] a drowsiness warning." 48 Fed. Reg. 48,576, 48,589 (Oct. 19, 1983). In other words, the data was insufficient to demonstrate that the risk of drowsiness from DXM was so extreme as to warrant a mandatory label warning. The FDA never concluded that DXM presents no material risk of drowsiness. To the contrary, the FDA recognized that cough suppressants such as DXM might trigger "a secondary pharmacological action … tantamount to a sedative effect" and that multiple references found drowsiness to be a side effect. *Id.* So far from concluding that DXM does not cause drowsiness, the FDA acknowledged evidence that DXM does cause drowsiness.

59. Moreover, the FDA evaluated the need for a drowsiness warning in the 1980s. Since then, more evidence has come out showing that DXM causes drowsiness. This is why reliable sources, like the NIH Library of Medicine, warn that DXM causes drowsiness. *Id.* It is why the UK patient leaflet for Robitussin products with DXM, which was prepared by GSK in "December 2020," identifies drowsiness as a side effect of DXM and warns against driving while taking the medicine because it can make you "sleepy." It is also why US regulators that have looked at the issue more recently, such as the FAA, have taken affirmative steps to address this danger, such as prohibiting pilots who have taken DXM from flying. This recent evidence (not before the FDA at the time) confirms that it is false and misleading to label drugs with DXM "Non-Drowsy." It also shows why the FDA's 1980s decision not to require an affirmative drowsiness warning—which was expressly based on lack of data—should not be interpreted to give drugmakers today, who now know better, a license to falsely assert that their cough medicines are "Non-Drowsy."

## V. Class action allegations.

60. Plaintiffs bring certain claims on behalf of the proposed class of: all persons who purchased a Non-Drowsy Robitussin Product in the United States during the applicable statute of limitations (the "**Nationwide Class**").

61. For certain claims, Plaintiffs bring those claims on behalf of a subclass of consumers who live in certain identified states (the "**Consumer Protection Subclass**").

62. For certain claims, Plaintiffs bring those claims on behalf of a subclass of consumers who, like Plaintiffs, purchased Non-Drowsy Robitussin Products in New York (the "**New York Subclass**").

63. The following people are excluded from the Class and the Subclasses: (1) any Judge or Magistrate Judge presiding over this action and the members of their family; (2) Defendants, Defendants' subsidiaries, parents, successors, predecessors, and any entity in which the Defendants or its parents have a controlling interest and their current employees, officers and directors; (3) persons who properly execute and file a timely request for exclusion from the Class; (4) persons whose claims in this matter have been finally adjudicated on the merits or otherwise released; (5) Plaintiffs' counsel and Defendants' counsel, and their experts and consultants; and (6) the legal representatives, successors, and assignees of excluded persons.

***Numerosity***

64. The proposed class(es) contain members so numerous that separate joinder of each member of the class is impractical. Based on the pervasive distribution of Non-Drowsy Robitussin Products, there are millions of proposed class members.

***Commonality***

65. There are questions of law and fact common to the proposed class(es). Common

questions of law and fact include, without limitation:

- Whether the Non-Drowsy Robitussin Products cause drowsiness;
- Whether Defendants' labeling of the Non-Drowsy Robitussin Products as "Non-Drowsy" is misleading;
- Whether Defendants violated state consumer protection statutes;
- Whether Defendants committed a breach of express warranty; and,
- Damages needed to reasonably compensate Plaintiffs and the proposed class(es).

***Typicality***

66. Plaintiffs' claims are typical of the proposed class(es). Like the proposed class(es), Plaintiffs purchased Non-Drowsy Robitussin Products. Like the proposed class(es), Plaintiffs would not have purchased the products, or would have paid less for them, had they known that they cause drowsiness.

***Predominance and Superiority***

67. The prosecution of separate actions by individual members of the proposed class(es) would create a risk of inconsistent or varying adjudication with respect to individual members, which would establish incompatible standards for the parties opposing the class. For example, individual adjudication would create a risk that breach of the same express warranty is found for some proposed class members, but not others.

68. Common questions of law and fact predominate over any questions affecting only individual members of the proposed class(es). These common legal and factual questions arise from certain central issues which do not vary from class member to class member, and which may be determined without reference to the individual circumstances of any particular class member. For example, a core liability question is common: whether Defendants' "Non-Drowsy" labelling is misleading to reasonable consumers.

69. A class action is superior to all other available methods for the fair and efficient adjudication of this litigation because individual litigation of each claim is impractical. It would be unduly burdensome to have individual litigation of millions of individual claims in separate lawsuits, every one of which would present the issues presented in this lawsuit.

## VI. Claims.

### Count I: Violations of State Consumer Protection Acts
### (on behalf of Plaintiffs and the Consumer Protection Subclass)

70. Plaintiffs incorporate by reference each and every factual allegation set forth above.

71. As alleged below, Plaintiffs (who live in New York) bring their individual and certain subclass claims based on New York consumer protection laws. At the motion to dismiss stage (pre-certification), their claims are governed by New York law. At certification, Plaintiffs intend to certify this count on behalf of the Consumer Protection Subclass, which includes consumers who live in the states listed below, which have materially-similar laws.

| State | Statute |
|---|---|
| California | Cal. Bus. & Prof. Code § 17200, and the following; *Id.* §17500, and the following; Cal. Civ. Code §1750 and the following. |
| Connecticut | Conn. Gen Stat. Ann. § 42- 110, and the following. |
| Washington, D.C. | D.C. Code § 28-3901, and the following. |
| Illinois | 815 ILCS § 501/1, and the following. |
| Maryland | Md. Code Ann. Com. Law, § 13-301, and the following. |
| Missouri | Mo. Rev. Stat. § 407, and the following. |
| New York | N.Y. Gen. Bus. Law § 349, and the following. |
| Washington | Wash. Rev. Code § 19.86.010, and the following. |

72. Each of these statutes is materially similar to New York consumer protection law. Each broadly prohibits deceptive conduct in connection with the sale of goods to consumers. No state requires proof of individualized reliance, or proof of defendant's knowledge or intent to deceive. Instead, it is sufficient that the deceptive conduct is misleading to reasonable consumers acting reasonably under the circumstances and that the conduct proximately caused harm. As alleged in detail above, Defendants' conduct violates each statute's shared prohibitions.

73. Defendants' "Non-Drowsy" misrepresentations were material. As alleged in detail above, these "Non-Drowsy" misrepresentations were important to consumers and affected their choice to purchase Non-Drowsy Robitussin Products. And, as alleged in detail above, these misrepresentations were likely to mislead reasonable consumers.

74. Defendants' misrepresentations were a substantial factor in Plaintiffs' purchase decisions and the purchase decisions of class members.

75. Plaintiffs and Subclass members were injured as a direct and proximate result of Defendants' conduct because (a) they would not have purchased Non-Drowsy Robitussin Products if they had known that the products cause drowsiness; (b) they overpaid for the products because the products are sold at a price premium due to the misrepresentation; or (c) they received products that were worthless for their intended purpose.

**Count II: Violation of New York's Gen. Bus. Law § 349**
**(on behalf of Plaintiffs and the New York Subclass)**

76. Plaintiffs incorporate by reference each and every factual allegation set forth above.

77. Plaintiffs bring this cause of action individually and for the New York Subclass, seeking statutory damages available under New York Gen. Bus. Law § 349 (among other relief).

78. Plaintiffs and the Subclass purchased Non-Drowsy Robitussin Products in New York.

79. Defendants' false and misleading "Non-Drowsy" claims are consumer-oriented. Defendants' misrepresentations have a broad impact on consumers at large, i.e., the hundreds of thousands (or potentially millions) of New Yorkers that purchase these products. These transactions recur every day.

80. Defendants' "Non-Drowsy" misrepresentations were material. As alleged in detail above, these "Non-Drowsy" misrepresentations were important to consumers and affected their choice to purchase Non-Drowsy Robitussin Products. And, as alleged in detail above, these misrepresentations were likely to mislead reasonable consumers.

81. As alleged in detail above, Defendants' misrepresentations were willful and knowing.

82. Plaintiffs and Subclass members were injured as a direct and proximate result of Defendants' conduct, and this conduct was a substantial factor in causing them harm, because they did not get what they paid for (cough syrup that was truthfully "Non-Drowsy") and they overpaid for the products because they are sold at a price premium due to Defendants' misrepresentations.

83. Plaintiffs and the Subclass seek statutory damages of $50, treble damages, reasonable attorney fees, and all other available relief. See N.Y.Gen.Bus.Law § 349 (h).

**Count III: Violation of New York Gen. Bus. Law § 350**
**(on behalf of Plaintiffs and the New York Subclass)**

84. Plaintiffs incorporate by reference each and every factual allegation set forth above.

85. Plaintiffs bring this cause of action individually and for the New York Subclass,

seeking statutory damages available under New York Gen. Bus. Law § 350 (among other relief).

86. Plaintiffs and the Subclass purchased Non-Drowsy Robitussin Products in New York.

87. Defendants' false and misleading "Non-Drowsy" claims impacted consumers at large. Defendants' misrepresentations have a broad impact on consumers at large, i.e., the hundreds of thousands (or potentially millions) of New Yorkers that purchase Non-Drowsy Robitussin Products. These transactions recur every day.

88. Defendants' "Non-Drowsy" claims were deceptive and misleading in a material way. As alleged in detail above, these "Non-Drowsy" misrepresentations were important to consumers and affected their choice to purchase Non-Drowsy Robitussin Products. And these misrepresentations were likely to mislead reasonable consumers.

89. Plaintiffs and the Subclass saw and relied on Defendants' "Non-Drowsy" misrepresentations.

90. As alleged in detail above, Defendants' misrepresentations were willful and knowing.

91. Plaintiffs and Subclass members were injured as a direct and proximate result of Defendants' conduct, and this conduct was a substantial factor in causing them harm, because they did not get what they paid for (cough syrup that was truthfully "Non-Drowsy") and they overpaid for the products because the products are sold at a price premium due to Defendants' misrepresentations.

92. Plaintiffs and the Subclass seek statutory damages of $500, treble damages, reasonable attorney fees, and all other available relief. See N.Y.Gen.Bus.Law § 350-e (3).

**Count IV: Breach of Express Warranty**
**(on behalf of Plaintiffs and a Nationwide Class)**

93. Plaintiffs incorporate by reference each and every factual allegation set forth above.

94. Plaintiffs bring this count individually and for the Nationwide Class.

95. Defendants, as the designers, manufacturers, marketers, distributors, suppliers, and/or seller of the Non-Drowsy Robitussin Products, issued material, written warranties by representing that the products were "Non-Drowsy." This was an affirmation of fact about the products (i.e., a description of the effects of the ingredients) and a promise relating to the goods.

96. This warranty was part of the basis of the bargain.

97. The Non-Drowsy Robitussin Products do not conform to the above-referenced representation because, as alleged in detail above, they cause drowsiness. Thus, the warranty was breached.

98. Plaintiff Calchi provided Defendants with classwide notice of this breach of warranty, by mailing a notice letter to Defendants' headquarters, on February 9, 2022.

99. Plaintiffs and the Nationwide Class were injured as a direct and proximate result of Defendants' breach, and this breach was a substantial factor in causing harm, because (a) they would not have purchased Non-Drowsy Robitussin Products if they had known that the products cause drowsiness; (b) they overpaid for the products because they are sold at a price premium due to the warranty; or (c) they received products that were worthless for their intended purpose.

## VII. Jury demand.

100. Plaintiffs demand a jury trial on all issues so triable.

## VIII. Relief.

101. Plaintiffs seek the following relief individually and for the proposed class(es):

- An order certifying the asserted claims, or issues raised, as a class action;
- A judgment in favor of Plaintiffs and the proposed class(es);
- Damages, statutory damages (including under N.Y.Gen.Bus.Law § 349 (h) and § 350-e (3)), treble damages, and punitive damages where applicable;
- Restitution;
- Disgorgement, and other just equitable relief;
- Pre- and post-judgment interest;
- Reasonable attorneys' fees and costs, as allowed by law;
- Any additional relief that the Court deems reasonable and just.

Date: June 15, 2022

Respectfully submitted,

By: */s/ Jonas B. Jacobson*

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